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AND G.D. SEARLE LLC

15 UNITED STATES DISTRICT COURT
16 NORTHERN DISTRICT OF CALIFORNIA
17 SAN FRANCISCO DIVISION
18

19 IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
20 PRODUCTS LIABILITY LITIGATION

21 *This document relates to*

22 MIKE TAYLOR, Individually and for the Estate of
MARY KATHLEEN TAYLOR, Deceased,

23 Plaintiff,

24 vs.

25 PFIZER, INC., PHARMACIA CORPORATION,
26 and G.D. SEARLE LLC, (FKA G.D. SEARLE &
CO.),

27 Defendants.
28

) MDL Docket No. 1699

) CASE NO. 3:07-cv-2576-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 ("Searle"), (collectively "Defendants") and file this Answer to Plaintiff's Complaint
4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Decedent was prescribed or used
8 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
9 generally. Defendants may seek leave to amend this Answer when discovery reveals the
10 specific time periods in which Decedent was prescribed and used Celebrex®.

11 **II.**

12 **ANSWER**

13 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,
14 Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny
15 that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain periods
16 of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
17 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
18 with their approval by the FDA. Defendants admit that, during certain periods of time,
19 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
20 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
22 FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent
27 injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Parties

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, marital status, and whether Plaintiff represents the Estate of Mary Kathleen Taylor, Deceased, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including Texas, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted

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1 Celebrex® in the United States, including Hawaii and California, to be prescribed by healthcare
2 providers who are by law authorized to prescribe drugs in accordance with their approval by the
3 FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 5. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
5 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
6 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
7 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
8 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
9 Celebrex® in the United States to be prescribed by healthcare providers who are by law
10 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
11 that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle
12 and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this
13 paragraph of the Complaint.

14 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
15 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
16 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
17 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
18 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
19 Celebrex® in the United States to be prescribed by healthcare providers who are by law
20 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
21 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
22 prescribing information. Defendants state that the potential effects of Celebrex® were and are
23 adequately described in its FDA-approved prescribing information, which was at all times
24 adequate and comported with applicable standards of care and law. Defendants deny any
25 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

26 7. Defendants state that the allegations in this paragraph of the Complaint regarding
27 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
28 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny

1 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 **Response to Allegations Regarding Jurisdiction and Venue**

3 8. Defendants are without knowledge or information to form a belief as to the truth of the
4 allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's citizenship
5 and the amount in controversy, and, therefore, deny the same. However, Defendants admit that
6 Plaintiff claims that the parties are diverse and the amount in controversy exceeds \$75,000,
7 exclusive of interests and costs.

8 9. Defendants are without knowledge or information to form a belief as to the truth of the
9 allegations in this paragraph of the Complaint regarding the judicial district in which the
10 asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex®
11 was and is safe and effective when used in accordance with its FDA-approved prescribing
12 information. Defendants deny committing a tort in the State of Texas or the State of California
13 and deny the remaining allegations in this paragraph of the Complaint.

14 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
15 and co-promoted Celebrex® in the United States, including Hawaii and California, to be
16 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
17 with their approval by the FDA. Defendants admit that, during certain periods of time,
18 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
19 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
20 providers who are by law authorized to prescribe drugs in accordance with their approval by the
21 FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in
22 the States of Hawaii, Texas, and California. Defendants state that the allegations in this
23 paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous.
24 Defendants are without knowledge or information sufficient to form a belief as to the truth of
25 such allegations, and, therefore, deny the same. Defendants deny committing a tort in the State
26 of Hawaii, the State of Texas, or the State of California and deny the remaining allegations in
27 this paragraph of the Complaint.

28

Response to Allegations Regarding Interdistrict Assignment

11. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

Response to Factual Allegations

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Decedent's medical condition or whether Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

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15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

17. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the remaining allegations in this paragraph of the Complaint.

18. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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19. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

20. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

21. Defendants state that the allegations in this paragraph of the Complaint regarding “other pharmaceutical companies” are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to provide the proper context for the remaining allegations in this paragraph and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

22. Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-

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1 approved prescribing information. Defendants state that the potential effects of Celebrex®
2 were and are adequately described in its FDA-approved prescribing information, which was at
3 all times adequate and comported with applicable standards of care and law. Defendants deny
4 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

5 23. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
6 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
7 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of
8 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
9 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
10 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis
11 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny
12 the remaining allegations in this paragraph of the Complaint.

13 24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
14 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
15 Celebrex® in the United States to be prescribed by healthcare providers who are by law
16 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
17 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
18 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
19 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
20 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
21 and effective when used in accordance with its FDA-approved prescribing information.
22 Defendants state that the potential effects of Celebrex® were and are adequately described in its
23 FDA-approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 25. Defendants state that the referenced article speaks for itself and respectfully refer the
27 Court to the article for its actual language and text. Any attempt to characterize the article is
28 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
2 this paragraph of the Complaint.

3 26. Defendants state that the referenced article speaks for itself and respectfully refer the
4 Court to the article for its actual language and text. Any attempt to characterize the article is
5 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
7 this paragraph of the Complaint.

8 27. Defendants state that the referenced FDA Update speaks for itself and respectfully refer
9 the Court to the FDA Update for its actual language and text. Any attempt to characterize the
10 FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when
11 used in accordance with its FDA-approved prescribing information. Defendants state that the
12 potential effects of Celebrex® were and are adequately described in its FDA-approved
13 prescribing information, which was at all times adequate and comported with applicable
14 standards of care and law. Defendants deny the remaining allegations in this paragraph of the
15 Complaint.

16 28. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny the remaining allegations in this paragraph of the Complaint.

21 29. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA
28 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to

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1 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
2 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself
3 and respectfully refer the Court to the study for its actual language and text. Any attempt to
4 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
5 the Complaint.

6 31. Defendants state that the referenced article speaks for itself and respectfully refer the
7 Court to the article for its actual language and text. Any attempt to characterize the article is
8 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 32. Defendants state that the referenced study speaks for itself and respectfully refer the
10 Court to the study for its actual language and text. Any attempt to characterize the study is
11 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
12 paragraph of the Complaint.

13 33. Defendants state that the Medical Officer Review speaks for itself and respectfully refer
14 the Court to the Medical Officer Review for its actual language and text. Any attempt to
15 characterize the Medical Officer Review is denied. Defendants deny any wrongful conduct and
16 deny the remaining allegations in this paragraph of the Complaint.

17 34. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee
18 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual
19 language and text. Any attempt to characterize the transcripts is denied. Defendants deny any
20 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

21 35. Defendants state that the referenced articles speak for themselves and respectfully refer
22 the Court to the articles for their actual language and text. Any attempt to characterize the
23 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
24 refer the Court to the study for its actual language and text. Any attempt to characterize the
25 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 36. Defendants state that the referenced article speaks for itself and respectfully refer the
27 Court to the article for its actual language and text. Any attempt to characterize the article is
28 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this

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1 paragraph of the Complaint.

2 37. Defendants state that the referenced articles speak for themselves and respectfully refer
3 the Court to the articles for their actual language and text. Any attempt to characterize the
4 articles is denied. Defendants deny the remaining allegations in this paragraph of the
5 Complaint.

6 38. Defendants state that the referenced article speaks for itself and respectfully refer the
7 Court to the article for its actual language and text. Any attempt to characterize the article is
8 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
9 Court to the study for its actual language and text. Any attempt to characterize the study is
10 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 39. Defendants state that the referenced Medical Officer Review speaks for itself and
12 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
13 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
14 allegations in this paragraph of the Complaint.

15 40. Plaintiff fails to provide the proper context for the allegations concerning “Public
16 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
17 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 41. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
22 paragraph of the Complaint.

23 42. Defendants state that the referenced study speaks for itself and respectfully refer the
24 Court to the study for its actual language and text. Any attempt to characterize the study is
25 denied. Plaintiff fails to provide the proper context for the allegations concerning “Public
26 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
27 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 43. Defendants admit that there was a clinical trial called APC. Defendants state that the
2 referenced article speaks for itself and respectfully refer the Court to the article for its actual
3 language and text. Any attempt to characterize the article is denied. Defendants deny the
4 remaining allegations in this paragraph of the Complaint.

5 44. Defendants state that the referenced article speaks for itself and respectfully refer the
6 Court to the article for its actual language and text. Any attempt to characterize the article is
7 denied. Plaintiff fails to provide the proper context for the allegations concerning “Data Safety
8 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
9 information or knowledge to form a belief as to the truth of such allegations and, therefore,
10 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 45. Defendants state that the referenced article speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 46. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
15 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
16 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 47. Defendants state that the referenced Medical Officer Review speaks for itself and
19 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
20 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 48. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide
23 the proper context for the allegations concerning “other Celebrex trials” contained in this
24 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
25 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
26 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
27 that the referenced study speaks for itself and respectfully refer the Court to the study for its
28 actual language and text. Any attempt to characterize the study is denied. Defendants deny the

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1 remaining allegations in this paragraph of the Complaint.

2 49. Defendants state that the referenced article speaks for itself and respectfully refer the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 50. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
6 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
7 therefore lack sufficient information or knowledge to form a belief as to the truth of such
8 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for
9 themselves and respectfully refer the Court to the studies for their actual language and text.
10 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
11 this paragraph of the Complaint.

12 51. Defendants state that the referenced Medical Officer Review speaks for itself and
13 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
14 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
15 allegations in this paragraph of the Complaint.

16 52. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint
17 are not directed toward Defendants, and therefore no response is required. To the extent that a
18 response is deemed required, Plaintiff fails to provide the proper context for the allegations in
19 this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.
20 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
21 such allegations and, therefore, deny the same. Defendants state that the referenced study
22 speaks for itself and respectfully refer the Court to the study for its actual language and text.
23 Any attempt to characterize the study is denied. Defendants deny the remaining allegations in
24 this paragraph of the Complaint.

25 53. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
26 Complaint are not directed toward Defendants, and therefore no response is required. To the
27 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
28 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph

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1 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
2 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
3 referenced study speaks for itself and respectfully refer the Court to the study for its actual
4 language and text. Any attempt to characterize the study is denied. Defendants deny the
5 remaining allegations in this paragraph of the Complaint.

6 54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
7 Complaint are not directed toward Defendants, and therefore no response is required. To the
8 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
9 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
10 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
11 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
12 referenced study speaks for itself and respectfully refer the Court to the study for its actual
13 language and text. Any attempt to characterize the study is denied. Defendants state that the
14 referenced article speaks for itself and respectfully refer the Court to the article for its actual
15 language and text. Any attempt to characterize the article is denied. Defendants deny the
16 remaining allegations in this paragraph of the Complaint.

17 55. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants deny the allegations in this
19 paragraph of the Complaint.

20 56. Defendants state that the referenced article speaks for itself and respectfully refer the
21 Court to the article for its actual language and text. Any attempt to characterize the article is
22 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

23 57. Defendants state that allegations in this paragraph of the Complaint are not directed
24 toward Defendants, and therefore no response is required. To the extent that a response is
25 deemed required, Defendants state that the referenced article speaks for itself and respectfully
26 refer the Court to the article for its actual language and text. Any attempt to characterize the
27 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28 58. Defendants deny the allegations in this paragraph of the Complaint.

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59. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations contained in this paragraph of the Complaint.

60. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

61. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

62. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

63. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and November 14, 2000. Defendants state that the referenced letters speak for themselves and

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1 respectfully refer the Court to the letters for their actual language and text. Any attempt to
2 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph
3 of the Complaint.

4 65. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.
5 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
6 the letter for its actual language and text. Any attempt to characterize the letter is denied.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 66. Defendants state that the referenced article speaks for itself and respectfully refer the
9 Court to the article for its actual language and text. Any attempt to characterize the article is
10 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 67. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.
12 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
13 the letter for its actual language and text. Any attempt to characterize the letter is denied.
14 Defendants deny the remaining allegations in this paragraph of the Complaint.

15 68. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
20 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
21 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
22 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
23 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
24 United States to be prescribed by healthcare providers who are by law authorized to prescribe
25 drugs in accordance with their approval by the FDA. Defendants deny the remaining
26 allegations in this paragraph of the Complaint.

27 69. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
4 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
5 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
6 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
7 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
8 United States to be prescribed by healthcare providers who are by law authorized to prescribe
9 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a
10 prescription medication which is approved by the FDA for the following indications: (1) for
11 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
12 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
13 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
14 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
15 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
16 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
17 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this
18 paragraph of the Complaint.

19 70. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which at all times was adequate and comported with applicable standards of care and law.
23 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
24 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
25 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
26 that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

27 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
4 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
5 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
6 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
7 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
8 United States to be prescribed by healthcare providers who are by law authorized to prescribe
9 drugs in accordance with their approval by the FDA. Defendants deny the remaining
10 allegations in this paragraph of the Complaint.

11 72. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which at all times was adequate and comported with applicable standards of care and law.
15 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
16 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
17 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
18 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
19 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
20 United States to be prescribed by healthcare providers who are by law authorized to prescribe
21 drugs in accordance with their approval by the FDA. Defendants deny the remaining
22 allegations in this paragraph of the Complaint.

23 73. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

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74. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

75. Defendants deny the allegations in this paragraph of the Complaint.

76. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

78. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
2 remaining allegations in this paragraph of the Complaint.

3 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® are and were adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® are and were adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
14 the study for its actual language and text. Any attempt to characterize the study is denied.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 82. Defendants deny any wrongful conduct and deny the remaining allegations in this
18 paragraph of the Complaint.

19 83. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
21 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® are and were adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 **Response to First Cause of Action: Negligence**

28 84. Defendants incorporate by reference their responses to each paragraph of Plaintiff's

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1 Complaint as if fully set forth herein.

2 85. Defendants state that this paragraph of the Complaint contains legal contentions to
3 which no response is required. To the extent that a response is deemed required, Defendants
4 admit that they had duties as are imposed by law but deny having breached such duties.
5 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
6 FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 86. Defendants state that this paragraph of the Complaint contains legal contentions to
12 which no response is required. To the extent that a response is deemed required, Defendants
13 admit that they had duties as are imposed by law but deny having breached such duties.
14 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
15 FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 87. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
22 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
27 remaining allegations in this paragraph of the Complaint, including all subparts.

28 88. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
2 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-
5 approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
7 remaining allegations in this paragraph of the Complaint.

8 89. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 90. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
16 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
21 Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations
22 in this paragraph of the Complaint.

23 91. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
25 medical conditions and whether Decedent used Celebrex®, and, therefore, deny the same.
26 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent
27 injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

28 92. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or

1 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
2 Complaint.

3 93. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
4 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
5 Complaint.

6 **Response to Second Cause of Action: Strict Liability**

7 94. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
8 Complaint as if fully set forth herein.

9 95. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
11 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
12 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
13 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
14 with their approval by the FDA. Defendants admit that, during certain periods of time,
15 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
16 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
17 providers who are by law authorized to prescribe drugs in accordance with their approval by the
18 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
19 consumers without substantial change from the time of sale. Defendants deny the remaining
20 allegations in this paragraph of the Complaint.

21 96. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 97. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
3 remaining allegations in this paragraph of the Complaint.

4 98. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
9 remaining allegations in this paragraph of the Complaint, including all subparts.

10 99. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
17 Celebrex® is defective, deny that Celebrex® caused Plaintiff or Decedent injury or damage,
18 and deny the remaining allegations in this paragraph of the Complaint.

19 100. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
24 remaining allegations in this paragraph of the Complaint.

25 101. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
4 Celebrex® is defective, deny that Celebrex® caused Plaintiff or Decedent injury or damage,
5 and deny the remaining allegations in this paragraph of the Complaint.

6 102. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 103. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
14 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
19 Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations
20 in this paragraph of the Complaint.

21 104. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 105. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7 106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
8 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
9 Complaint.

10 107. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
11 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
12 Complaint.

13 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
14 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
15 Complaint.

16 **Response to Third Cause of Action: Breach of Express Warranty**

17 109. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
18 Complaint as if fully set forth herein.

19 110. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants admit that they provided FDA-approved
26 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
27 this paragraph of the Complaint.

28 111. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
2 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-
5 approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants admit that they provided FDA-approved
7 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and
8 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

9 112. Defendants admit that they provided FDA-approved prescribing information regarding
10 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this
11 paragraph of the Complaint.

12 113. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 114. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 115. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
26 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants admit that they provided FDA-approved prescribing information regarding
2 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

3 116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
4 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
5 Complaint.

6 117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
7 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
8 Complaint.

9 118. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
10 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
11 Complaint.

12 **Response to Fourth Cause of Action: Breach of Implied Warranty**

13 119. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
14 Complaint as if fully set forth herein.

15 120. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
16 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
17 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
18 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
19 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
20 Celebrex® in the United States to be prescribed by healthcare providers who are by law
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
22 the remaining allegations in this paragraph of the Complaint.

23 121. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants admit that they provided FDA-approved prescribing information regarding
28 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 122. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 123. Defendants state that this paragraph of the Complaint contains legal contentions to
7 which no response is required. To the extent that a response is deemed required, Defendants
8 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
9 approved prescribing information. Defendants state that the potential effects of Celebrex®
10 were and are adequately described in its FDA-approved prescribing information, which was at
11 all times adequate and comported with applicable standards of care and law. Defendants deny
12 any wrongful conduct, deny that they breached any warranty, and deny the remaining
13 allegations in this paragraph of the Complaint.

14 124. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
16 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
17 medication which is approved by the FDA for the following indications: (1) for relief of the
18 signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid
19 arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of
20 primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
21 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
22 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the
23 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 125. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants admit that they provided FDA-approved
4 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
5 this paragraph of the Complaint.

6 126. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
8 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
9 Celebrex® was expected to reach users and consumers without substantial change from the
10 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 127. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
13 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they
18 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

19 128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
20 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
21 Complaint.

22 129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
23 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
24 Complaint.

25 130. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
26 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
27 Complaint.

28

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Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment

131. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

132. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

134. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

135. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
4 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this
5 paragraph of the Complaint, including all subparts.

6 136. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 137. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
14 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
19 remaining allegations in this paragraph of the Complaint.

20 138. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
22 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
27 remaining allegations in this paragraph of the Complaint.

28 139. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
2 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-
5 approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
7 remaining allegations in this paragraph of the Complaint.

8 140. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
10 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
15 remaining allegations in this paragraph of the Complaint.

16 141. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
18 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
23 remaining allegations in this paragraph of the Complaint.

24 142. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
26 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

1 approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
3 remaining allegations in this paragraph of the Complaint.

4 143. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
5 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
6 Complaint.

7 144. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
8 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
9 Complaint.

10 145. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
11 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
12 Complaint.

13 **Response to Sixth Cause of Action: Unjust Enrichment**

14 146. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
15 Complaint as if fully set forth herein.

16 147. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
17 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
18 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
19 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
20 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
21 Celebrex® in the United States to be prescribed by healthcare providers who are by law
22 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
23 the remaining allegations in this paragraph of the Complaint.

24 148. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
26 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
27 paragraph of the Complaint.

28 149. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
2 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
3 paragraph of the Complaint.

4 150. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
6 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
11 remaining allegations in this paragraph of the Complaint.

12 151. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used
14 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
19 remaining allegations in this paragraph of the Complaint.

20 152. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
21 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
22 Complaint.

23 **Response to Seventh Cause of Action:**

24 **State Consumer Fraud and Deceptive Trade Practices Act**

25 153. Answering the second Paragraph 158 in the Complaint, Defendants incorporate by
26 reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

27 154. Defendants state that this paragraph of the Complaint contains legal contentions to
28 which no response is required. To the extent that a response is deemed required, Defendants

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1 admit that they had duties as are imposed by law but deny having breached such duties.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 155. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations regarding whether Decedent used Celebrex® and, therefore, deny the
5 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 156. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations regarding whether Decedent used Celebrex® and, therefore, deny the
13 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent
18 injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

19 157. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Decedent used Celebrex® and, therefore, deny the
21 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 158. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations regarding whether Decedent used Celebrex® and, therefore, deny the
24 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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the Complaint.

159. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

160. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

161. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

162. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

163. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

164. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer For Relief

Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in paragraph of the Complaint headed "Prayer for Relief," including all subparts.

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff and Decedent were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff or Decedent were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff or Decedent.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Decedent's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the

time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff and Decedent was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff's and Decedent's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiff and Decedent knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because

1 the subject pharmaceutical product at issue was subject to and received pre-market approval by
2 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

3 **Twenty-second Defense**

4 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
5 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
6 and Plaintiff's causes of action are preempted.

7 **Twenty-third Defense**

8 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
9 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
10 issue under applicable federal laws, regulations, and rules.

11 **Twenty-fourth Defense**

12 24. Plaintiff's claims are barred in whole or in part because there is no private right of
13 action concerning matters regulated by the Food and Drug Administration under applicable
14 federal laws, regulations, and rules.

15 **Twenty-fifth Defense**

16 25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate
17 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning
18 of Comment j to Section 402A of the Restatement (Second) of Torts.

19 **Twenty-sixth Defense**

20 26. Plaintiff's claims are barred or limited to a product liability failure to warn claim
21 because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of
22 Restatement (Second) of Torts § 402A, Comment k.

23 **Twenty-seventh Defense**

24 27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical
25 product at issue "provides net benefits for a class of patients" within the meaning of Comment f
26 to § 6 of the Restatement (Third) of Torts: Products Liability.

27 **Twenty-eighth Defense**

28 28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts:

Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of Texas and California, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff and Decedent failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of Texas and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff or Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff or Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance*

1 *Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559
2 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

3 **Thirty-ninth Defense**

4 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
5 and marketing of Celebrex®, if any, used in this case, included adequate warnings and
6 instructions with respect to the product's use in the package insert and other literature, and
7 conformed to the generally recognized, reasonably available, and reliable state of the
8 knowledge at the time the product was marketed.

9 **Fortieth Defense**

10 40. The claims asserted in the Complaint are barred because Celebrex® was designed,
11 tested, manufactured and labeled in accordance with the state-of-the art industry standards
12 existing at the time of the sale.

13 **Forty-first Defense**

14 41. If Plaintiff or Decedent has sustained injuries or losses as alleged in the Complaint,
15 upon information and belief, such injuries and losses were caused by the actions of persons not
16 having real or apparent authority to take said actions on behalf of Defendants and over whom
17 Defendants had no control and for whom Defendants may not be held accountable.

18 **Forty-second Defense**

19 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
20 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
21 intended, and was distributed with adequate and sufficient warnings.

22 **Forty-third Defense**

23 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,
24 waiver, and/or estoppel.

25 **Forty-fourth Defense**

26 44. Plaintiff's claims are barred because Plaintiff's and Decedent's injuries, if any, were the
27 result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions,
28 diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff

and Decedent, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff or Decedent.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff and Decedent did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff and Decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged

1 injuries and damages, if any, of Plaintiff and Decedent.

2 **Fifty-second Defense**

3 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the
4 common law gives deference to discretionary actions by the United States Food and Drug
5 Administration under the Federal Food, Drug, and Cosmetic Act.

6 **Fifty-third Defense**

7 53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
8 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
9 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's
10 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
11 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
12 and with the specific determinations by FDA specifying the language that should be used in the
13 labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the
14 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
15 United States.

16 **Fifty-fourth Defense**

17 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
18 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

19 **Fifty-fifth Defense**

20 55. Defendants state on information and belief that the Complaint and each purported cause
21 of action contained therein is barred by the statutes of limitations contained in California Code
22 of Civil Procedure §§ 335.1 and 3338 and former § 340(3), and such other statutes of limitation
23 as may apply.

24 **Fifty-sixth Defense**

25 56. Defendants state on information and belief that any injuries, losses, or damages suffered
26 by Plaintiff and Decedent were proximately caused, in whole or in part, by the negligence or
27 other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's
28 recovery against Defendants, if any, should be reduced pursuant to California Civil Code §

1 1431.2.

2 **Fifty-seventh Defense**

3 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
4 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
5 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
6 damages is also barred under California Civil Code § 3294(b).

7 **Fifty-eighth Defense**

8 58. Plaintiff's causes of action are barred by Texas Civil Practice & Remedies Code §
9 82.007.

10 **Fifty-ninth Defense**

11 59. Plaintiff's causes of action are barred by Texas Civil Practice & Remedies Code §
12 82.003.

13 **Sixtieth Defense**

14 60. Plaintiff's causes of action are barred by Texas Civil Practice & Remedies Code §
15 16.012.

16 **Sixty-first Defense**

17 61. This action is subject to the proportionate responsibility provisions of Chapter 33 of the
18 Texas Civil Practice and Remedies Code, including (without limitation) the requirement of §
19 33.003 thereof that the trier of fact determine the relative responsibility of each claimant,
20 Defendants, and responsible third-party that may be joined in the suit.

21 **Sixty-second Defense**

22 62. If Plaintiff settles with any other person or entity, then Defendants reserve the right to
23 make a written election of credit for settlements under § 33.014 of the Texas Civil Practice and
24 Remedies Code.

25 **Sixty-third Defense**

26 63. Plaintiff's claims are barred, in whole or in part, by the doctrine of accord and
27 satisfaction.

28

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Sixty-fourth Defense

64. Plaintiff's claims are barred in whole or in part because any alleged defect was not known or not reasonably scientifically knowable at the time the product was distributed.

Sixty-fifth Defense

65. Plaintiff's claims are barred by Plaintiff's and Decedent's failure to comply with conditions precedent to the right to recover.

Sixty-sixth Defense

66. Plaintiff's claims are barred in whole or in part by the doctrine of informed consent. Decedent was informed of the risks associated with treatment and willingly consented to treatment despite those risks. Specifically, Decedent gave informed consent to the prescribing physicians before taking Celebrex®, alone or in combination with any other drug(s).

Sixty-seventh Defense

67. The duty to obtain Decedent's informed consent prior to prescribing Celebrex® alone or in combination with any other drug(s) rested solely with the prescribing physicians.

Sixty-eighth Defense

68. Plaintiff may not assert a claim against Defendants for negligent misrepresentation as Plaintiff and Decedent did not suffer a pecuniary loss as a result of any alleged misrepresentation by Defendants.

Sixty-ninth Defense

69. Plaintiff's claims of negligent misrepresentation are barred by the failure to justifiably rely on any alleged misrepresentation of Defendants.

Seventieth Defense

70. Plaintiff's claims of misrepresentation are barred because any alleged misrepresentation on which Plaintiff or Decedent relied did not constitute a misrepresentation of material facts.

Seventy-first Defense

71. Plaintiff's claims for breach of warranty are barred in whole or in part by the Defendants' disclaimers.

Seventy-second Defense

72. Plaintiff's claims for breach of warranty are barred in whole or in part because Plaintiff and Decedent are not in privity with Defendants.

Seventy-third Defense

73. Defendants assert the defenses of expiration, limitation, and exclusion to any applicable express or implied warranty, if any be proved.

Seventy-fourth Defense

74. Plaintiff's claims are barred in whole or in part because any warranties, if made, are excluded through course of dealing, course of performance and/or usage of trade.

Seventy-fifth Defense

75. Plaintiff has failed to allege conduct warranting imposition of punitive damages under Texas law.

Seventy-sixth Defense

76. The standards in Texas governing the award and review of damages for non-pecuniary damages, including damages for mental anguish and pain and suffering, are impermissibly vague or simply non-existent, and are inadequate to ensure that such awards do not include amounts intended as exemplary damages, which are impermissible in a compensatory damages award.

Seventy-seventh Defense

77. Plaintiff's claims for punitive or exemplary damages are subject to the limitations and requirements of Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in Section 41.008(b).

Seventy-eighth Defense

78. Because of the lack of clear standards, the imposition of punitive damages against Defendants is unconstitutionally vague and/or overbroad.

Seventy-ninth Defense

79. No act or omission of Defendants was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

Eightieth Defense

80. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's and Decedent's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's and Decedent's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

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1 July 24, 2007

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

July 30, 2007

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